

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Michael W. Dahm, et al. Art Unit : 1634
Serial No. : 09/601,645 Examiner : J. Goldberg
Filed : August 4, 2000 Customer No.: 20985
Conf. No. : 7793
Title : METHOD FOR QUANTITATIVELY ANALYZING TUMOR CELLS IN A
BODY FLUID AND TEST KITS SUITED THEREFOR

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

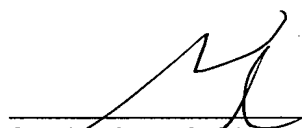
TRANSMITTAL LETTER

Sir:

Transmitted herewith are a Transmittal Letter (1 page in duplicate); Issue Fee Transmittal PTOL-85 (Part B) (1 page); Comments on Statement of Reasons for Allowance (4 pages); a check in the amount of \$ 707.00 for the Issue Fee (Small Entity), and an Advance Order of 14 copies of the issued patent; and a return postcard for filing in connection with the above-identified application.

- ☒ The Commissioner is hereby authorized to charge any fee, including any submitted herewith, if the attached check(s) is in the wrong amount or otherwise improper or missing, that may be due in connection with this and the attached papers, or with this application during its entire pendency, or to credit any overpayment to Deposit Account No. 06-1050.

Respectfully submitted,


Stephanie L. Seidman
Reg. No. 33,779

Attorney Dkt. No. 17164-008US1 (24741-1509US)

Address all correspondence to:

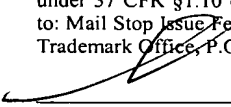
Stephanie Seidman
Fish & Richardson P.C.
12390 El Camino Real
San Diego, California 92130
Telephone: (858) 678-4777
Facsimile: (202) 626-7796
seidman@fr.com
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Stephanie L. Seidman



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COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

Dear Sir:

Consideration of the following Comments on Statement of Reasons for Allowance is respectfully requested:

REMARKS

Any fees that may be due in connection with filing this paper may be charged to Deposit Account No. 06-1050.

Comments on Examiner's Statement of Reasons for Allowance

The Examiner states that the claims have been placed in condition for allowance in view of the amendment to require a range of 1.060-1.065 g/ml cell separation medium density and the Declaration filed by Dr. Michael Dahm (hereinafter, "Declaration"). The Examiner further states that, as demonstrated by the Declaration, a range of 1.060 – 1.065 g/ml ensures quantification of tumor cells rather than non tumor cells or telomerase-positive non tumor cells because of the unexpected result that a cell separation medium density of at least 1.060 g/ml is necessary to avoid significant tumor cell loss, while a range of 1.065 g/ml or less prevents contamination of the tumor cell fraction with telomerase-positive non-tumor cells.

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Stephanie L. Seidman

Applicant further submits that the claims are allowable for a number of reasons. For example, none of the references cited during prosecution, singly or in any combination, discloses, teaches or suggests a general method for the quantification of tumor cells regardless of tumor cell type, nor performing such quantification by correlating tumor cell mRNA encoding the catalytic subunit of telomerase with the number of tumor cells. Therefore, the allowed claims are novel and non-obvious over the cited art.

For example, Cech et al. (U.S. Patent No. 6,166,178), is cited as allegedly teaching a method for the quantification of tumor cells by quantitating mRNA coding for the catalytic subunit of telomerase because the reference teaches amplification of the catalytic subunit of telomerase mRNA and correlation of the amplified mRNA with the number of tumor cells is allegedly acknowledged by Applicant as being "routine." As discussed in previous responses, whether or not correlation between a quantity of amplified marker mRNA and the number of cells expressing the mRNA is routine, there is no teaching or suggestion in Cech et al. of the desirability of performing the correlation, nor of quantitating tumor cells by any other method. Further, Van Vlasselaer (U.S. Patent No. 5,648, 223), directed to the concentration of breast cancer cells by centrifugation, and Bosslet et al. (Br. J. Cancer, 44:356-362, (1981)), directed to concentrating tumor cells, also do not teach or suggest quantitating tumor cells. Therefore, Van Vlasselaer and Bosslet et al. do not cure the deficiencies of Cech et al.

It is the instant application that teaches the quantification of tumor cells in a body fluid by centrifuging the tumor cell fraction and correlating the quantity of amplified tumor cell mRNA coding for the catalytic subunit of telomerase with the quantity of tumor cells in a body fluid. It is the instant application that teaches the desirability of quantitating tumor cells in a body fluid as an indication of metastasis (see, e.g., page 14, lines 24-26 and page 26, lines 3-11). None of Cech et al., Van Vlasselaer or Bosslet et al., nor any of the other references cited during prosecution of the instant application, singly or in any combination, teaches or suggests a method for the quantification of tumor cells in a body fluid by correlating the amount of amplified tumor cell mRNA coding for the catalytic subunit of telomerase with the number of tumor cells in the body fluid.

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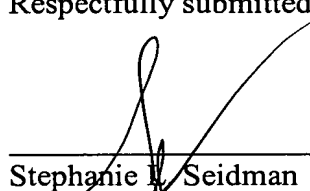
Attorney's Docket No.: 17164-008US1
(24741-1509US)

Claim 23

Claim 23 is directed to the method of Claim 1 where the cell separation medium used is Percoll or Ficoll. The Examiner is thanked for the courtesy of a telephonic interview dated March 24, 2004, concerning use of the trademarks Percoll and Ficoll in Claim 23. During the interview, the Examiner indicated that these trademarks are known since the 1970's and are therefore considered to be of a generic nature.

Entry of the above remarks in the file history of this application are respectfully requested.

Respectfully submitted,



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